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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/997,525 | 11/29/2001 | Erlinda M. Gordon | EPE1110-1 | 6086 |

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EXAMINER

MONTANARI, DAVID A

ART UNIT PAPER NUMBER

1632

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/997,525 | | GORDON ET AL. | |
| | Examiner | | Art Unit | |
| | David Montanari | | 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants arguments and amendments filed 11/28/2005 have been entered.
2. Claim 1 has been amended.
3. Claims 2, 4-8, and 11-26 are cancelled.
4. Claims 1, 3, and 9-10 are examined in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, and 9-10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hall et al (WO 98/44938, 15 October 1998) for reasons of record filed 7/28/2005.

Response to Arguments

Applicants argue in amendment that the Hall et al. reference does not teach all the limitations of the claimed invention. Specifically, applicants argue that Hall does not teach a retroviral particle comprising a von Willebrand factor collagen binding motif and a gene encoding GM-CSF. This is not persuasive. Hall does provide the teachings to anticipate the claimed invention. In paragraph 1 of Hall et al., it is stated "This invention further relates to "targeted" viral or non-viral particles, including retroviral particles..". In paragraph 38 of Hall et al. it is stated that "In a preferred embodiment, the vector particle having a modified envelope in

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accordance with the invention includes a polynucleotide encoding a heterologous polypeptide which is to be expressed in a desired cell". In paragraph 39 of Hall et al. it is stated that said heterologous polypeptide may in one embodiment be a therapeutic agent, wherein said therapeutic agent includes GM-CSF (parag. 40). In Example 1 of Hall et al. it is taught that the Cee+ vector comprises a modified collagen binding domain that was derived from a functional domain within von Willebrand Factor involved in the recognition of exposed vascular collagen sequences. Further Hall et al. teaches "This construct was designed specifically for targeting a retrovirus to collagen exposed by injury, inflammation, disease, or reparative surgical procedures". Hall et al. further teaches that "Cells which may be infected or transduced with the vector particles of the present invention include, but are not limited to, endothelial cells, tumor cells.." (parag. 59). A reading of the Hall et al. reference would provide sufficient guidance and teachings to the ordinary artisan that would anticipate the claimed invention. The 102b rejection does not require Hall et al. to exactly teach a vector comprising the vector that is claimed in the same language as claim 1. Hall et al. do provide the teachings of a retroviral vector, that will comprise GM-CSF a modified von Willebrand factor collagen binding motif, target tumor cells, and recruit host mononuclear cells to the site of the tumor. Hall et al. does not provide working examples of the claimed targeted retroviral vector particle targeting tumor cells, however the Hall et al. reference provides sufficient teachings throughout the entire reference to anticipate the claimed invention. Thus for reasons of record mailed 7/28/2005 and above the rejection is maintained.

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With regard to the 102(b) rejection filed on 12/28/2004 applicants argue that the ammendment to claim 1 "and wherein the cells of the tumor transduced by the vector express GM-CSF, resulting in the recruitment of host mononuclear cells to the site of the tumor", provides a limitation not anticipated by the art presented in the 102(b) rejection. This is not persausive. Hall et al. teaches a retroviral particle wherein the viral surface protein has been modified to include a targeting polypeptide that binds to an extracellular matrix component of a cell (including collagen) and the particle also comprises a therapeutic gene (including GM-CSF), and a method of delivering therapeutic genes to a tumor and a method of treatment. The recruitment of host mononuclear cells to the site of the tumor is inherent to the retroviral particle taught by Hall et al. and clearly anticipates the invention of claims 1, 3, and 9-10. The retroviral particle taught be Hall et al. would result in the recruitment of host mononuclear cells to the site of the tumor since it is identical to the claimed targeted retroviral particle of the instant application. Applicants do not provide any evidence as to how the vector used by Hall et al. (WO 98/44938, 15 October 1998), that is the same vector as claimed instantly will not have the functional characteristics claimed instantly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 3, and 9-10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al (WO 98/44938, 15 October 1998), or Hall et al. (Human Gene Therapy 11: 983-993, 2000), or Liu et al (J. of Virology 74: 5320-5328, 2000), Gordon et al (Cancer Res. 60: 3343-3347, 2000), in view of Kurane et al (Annals of Surgery 4: 579-585, 1997) and Borello et al (Human Gene Therapy 10: 1983-1991, 1999) for reasons of record set forth in the previous office actions of 8/21/03, 5/18/04, 4/4/2005 and 7/28/2005.

Response to Arguments

Applicant argues in amendment filed 11/28/2005 that the combined references are used in hindsight to base the 103 rejection of claim 1, 3, and 9-10. Applicant continues to argue that each reference alone does not provide the requisite teaching and motivation to the ordinary artisan to develop the claimed invention. This is not persuasive. As stated in the office actions dated 8/21/03, 5/18/04 and 4/4/2005, there is sufficient motivation and teachings to the ordinary artisan to make and use the claimed invention. Each reference does not need to teach every limitation of the claims, however the combined references do teach and motivate the ordinary artisan to make and use the claimed invention. Thus for reasons of record and above the rejection is maintained.

No claims are allowed.

Conclusion

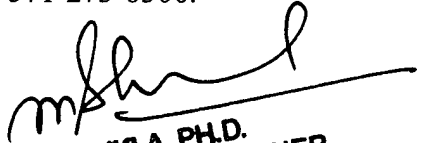
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David A. Montanari, PhD



RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER